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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/820,581

04/07/2004

Mark E. Deem

17315-002002

8576

20985 7590 05/22/2007

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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

05/22/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/820,581

Applicant(s)

DEEM ET AL.

Examiner

Lindsey Bachman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 23-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-21 and 23-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3-19-07, 12-20-06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to Applicant's amendment filed on 23 February 2007.

Information Disclosure Statement

The information disclosure statement filed 19 March 2007 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Copies of PCT/xx06/08634 AND PCT/xx06/116558 were not provided. Further, Applicant has not designated to what country the PCTs belong.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant does not disclose the deployment of two separate

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structures, as claimed in Claim 1, in the specification of the present application or in parents US Patent 6,629,534 or Provisional Application 60/128,690.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 11-16, 18, 20, 21, 24, 26, 27,30, 32-35 are rejected under 35

U.S.C. 102(e) as being anticipated by Oz, et al. (US Patent Number 6,269,819).

Claim 11 and 21 and 27: Oz'819 discloses a method of repairing a heart valve by advancing a catheter (column 6, lines 29-34) through a patient's vasculature (column 8, lines 19-21) having an annuloplasty device releasably attached (column 2, lines 47-54). The annuloplasty device (102 in Figure 13, for example) is deployed to hold the leaflets of the heart valve together and reduce regurgitation (column 2, lines 47-54). Holding the valve leaflets together also modifies the spatial relationship between first and second valve leaflets to reduce regurgitation of the heart valve.

3. Claim 12, 13, 14, 15, 16, 26, 33-35: Oz'819 discloses modifying the spatial relationship between the leaflets by clipping opposed points along the leaflets together (column 5, lines 46-56 and Figure 13). Further, regarding Claim 34, it is known that

chordae are part of the leaflets, therefore, the opposed chordae are linked when the opposed leaflets are attached.

4. Claim 18, 24, 30: Oz'819 discloses that the structure can be deployed on the atrial side of the annulus (column 7, lines 51-58).

5. Claim 20: Oz'819 discloses advancing the catheter through the interatrial septum of the heart (column 8, lines 28-30).

6. Claim 32: Oz'819 discloses that the fastener clips will be made out of nitinol, stainless steel or titanium, which are not bioabsorbable materials, so they will be in place permanently (column 5, lines 14-17).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oz'819 in view of Campbell'024.

8. Claim 1, 2, 3, 5: Oz'819 discloses a method of repairing a heart valve by advancing a catheter (column 6, lines 29-34) through a patient's vasculature (column 8, lines 19-21) having a fastener (second structure) releasably attached (column 2, lines 47-54). The fastener is deployed to hold the leaflets of the heart valve together and reduce regurgitation (column 2, lines 47-54). Oz'819 does not teach deploying a first structure (ring).

9. Campbell'024 teaches the use of a support ring used to surround the annulus in order to restore the natural size and shape of the annulus so that it can function normally (column 1, lines 18-22). It would have been obvious to deploy the ring device taught by Campbell'024 on the catheter taught by Oz'819 because it would repair a weakened valve and avoid performing open-heart surgery on a patient, which is preferably avoided due to the increased risk and lengthened recovery time.

10. Claim 4: Oz'819 discloses that the structure can be deployed on the atrial side of the annulus (column 7, lines 51-58).

11. Claim 6-9: Oz'819 discloses modifying the spatial relationship between the leaflets by clipping opposed points along the leaflets together (column 5, lines 46-56 and Figure 13). Oz'819 discloses that clips, staples, coils, sutures, dual button fasteners, cufflink-like fasteners can be used to fasten the valve leaflets together (column 6, lines 23-28).

12. Claim 10: Oz'819 discloses advancing the catheter through the

interatrial septum of the heart (column 8, lines 28-30).

13. Claims 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oz'819, as applied to Claim 11, in further view of Campbell, et al. (US Patent 6,143,024).

14. Claims 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oz'819, as applied to Claim 21, in further view of Campbell'024.

15. Claims 28, 29, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oz'819, as applied to Claim 27, in further view of Campbell'024.

16. Oz'819 discloses the limitations of Claims 17, 19, 23, 25, 28, 29 and 31 except for circumferentially shortening the annulus. Campbell'024 teaches the use of a support ring used to surround the annulus in order to restore the natural size and shape of the annulus so that it can function normally (column 1, lines 18-22). It would have been obvious to deploy the ring device taught by Campbell'024 on the catheter taught by Oz'819 because it would repair a weakened valve and avoid performing open-heart surgery on a patient, which is preferably avoided due to the increased risk and lengthened recovery time.

Response to Arguments

17. Applicant's arguments with respect to claims 1-35 have been considered but are moot in view of the new ground(s) of rejection.

18. Regarding Applicant's assertion that Oz does not mention deploying a structure near the annulus of a heart valve, Examiner points Applicant to Figures 13-17 and

column 5, line 40 to column 7, line 35 which clearly disclose deploying a structure near the annulus of a heart valve.

19. Applicant asserts that Oz does not disclose deploying a structure on the atrial side of the annulus. Examiner disagrees because Oz shows the leaflets are grabbed and a clip is attached at the point the leaflets are grabbed in Figure 13.

20. Applicant asserts that the chordae are distinct anatomical structures from valve leaflets. Examiner maintains that if leaflets are linked, the chordae attached to the leaflets are linked through the leaflets.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Imb

A handwritten signature in black ink, appearing to read "MJ Hayes", with a long horizontal flourish extending to the right.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER